

120.400: X-RAYS IN THE HEALING ARTS

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120.403: General Requirements

(A) Administrative Controls.

(1) Registrant. The registrant shall be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of 105 CMR 120.403(A)(1) are met in the operation of the x-ray system(s).

(a) An x-ray system which does not meet the provisions of 105 CMR 120.400 shall not be operated for diagnostic or therapeutic purposes, if so directed by the Radiation Control Program.

(b) Individuals who shall be operating the x-ray systems shall meet the requirements of 105 CMR 125.000: *Regulations Governing the Licensing of Radiologic Technologists*.

(c) A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for routine examinations performed with that system, the following information:

1. Patient's body size and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;
2. Type and size of the film or film-screen combination to be used;
3. Type and focal distance of the grid to be used, if any;
4. Source to image receptor distance to be used (except for dental intra-oral radiography); and,
5. Type and location of placement of patient shielding (*e.g.* gonad, *etc.*) to be used.

(d) The registrant of a facility shall create and make available to x-ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(e) Except for patients who cannot be moved out of the room, only the staff, ancillary personnel, and parents of pediatric patients whose presence might be required for the medical procedure or training shall be in the room or area during the radiographic exposure. Other than the patient being examined:

1. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.
2. Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.403: continued

3. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.
- (f) Gonad shielding of not less than 0.50 millimeter lead equivalent shall be used for patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.
- (g) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:
 1. Exposure of an individual for training, demonstration, or other non-healing-arts purposes; and,
 2. exposure of an individual for the purpose of healing arts screening except as authorized by 105 CMR 120.403(A)(1)(k).
- (h) When a patient or film must be provided with auxiliary support during a radiation exposure:
 1. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 105 CMR 120.403(A)(1)(d), shall list individual projections, specific patient conditions, or psychological development level where holding devices cannot be utilized;
 2. Written safety procedures, as required by 105 CMR 120.403(A)(1)(d), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;
 3. The human holder shall be protected as required by 105 CMR 120.403(A)(1)(e);
 4. No individual shall be used routinely to hold film or patients;
 5. In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and,
 6. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded.
- (i) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.
 1. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intra-oral use in dental radiography.
 2. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.
 3. Protective equipment including aprons, gloves, and shields shall be checked annually for defects, such as holes, cracks, and tears to assure reliability and integrity. A record of this test shall be maintained for inspection by the Radiation Control Program. If such defect is found, equipment shall be replaced or removed from service until repaired or replaced.
 4. Radiographic systems other than fluoroscopic, dental intra-oral, or veterinarian systems shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.
 5. Mammographic procedures shall only be performed on special purpose mammographic equipment.
 6. Mobile or portable radiographic systems shall only be used for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation
 7. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

105 CMR: DEPARTMENT OF PUBLIC HEALTH

- a. Be positioned properly, *i.e.*, tube facing the right direction, and grid centered to the central ray;
- b. If of the focus type, be of the proper focal distance for the SIDs being used.

105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.403: continued

- (j) All occupationally exposed individuals are subject to the requirements of 105 CMR 120.211, 120.215, 120.217 and 120.218.
 - (k) Healing Arts Screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Radiation Control Program. When requesting such approval, that person shall submit the information outlined in 105 CMR 120.421: *Appendix B*. If any information submitted to the Radiation Control Program becomes invalid or outdated, the Radiation Control Program shall be immediately notified.

(L) If the facility ceases to operate, the facility must notify the Radiation Control Program within 15 days. Included in this notification, is the name and address of the person who disposed of the x-ray unit.
 - (2) Information and Maintenance Record and Associated Information. The registrant shall maintain the following information for each x-ray system for inspection by the Radiation Control Program:
 - (a) Model and serial numbers of all major components, and user's manuals for those components;
 - (b) Records of installation, surveys, calibrations, maintenance, and modifications performed on the x-ray system(s) after the effective date of 105 CMR 120.000 with the names of persons who performed such services;

(1) A copy of the service providers certificate of registration shall be maintained by the facility.
 - (c) A scale drawing provided by a qualified expert of the room in which a stationary x-ray system is located with such drawing indicating the current use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:
 - 1. The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or,
 - 2. The type and thickness of materials, or lead equivalency, of each protective barrier; and,
 - (d) A copy of all correspondence with this Radiation Control Program regarding that x-ray system.
 - (3) X-Ray Utilization Log. Except for veterinary facilities, each facility shall maintain an x-ray record containing the patient's name, the type of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.
 - (4) Radiograph and Record Retention. Radiographs shall be retained for at least a minimum of five years following last visit of the patient. The written reports become a part of the patient's medical record and are to be retained for 30 years following last visit of patient.
- (B) Plan Review.
- (1) Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing x-rays for diagnostic or therapeutic purposes shall be submitted to the Radiation Control Program for review and approval. The required information is denoted in 105 CMR 120.420: *Appendix A* and 120.422: *Appendix B*, unless specifically exempted.
 - (2) The Radiation Control Program may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.
 - (3) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 105 CMR 120.211, 120.217, 120.218 and 120.221.
- (C) X-Ray Film Processing Facilities and Practices.
- (1) Each installation using a radiographic x-ray system and using analog image receptors (*e.g.* radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:
 - (a) Manually developed film:

105 CMR: DEPARTMENT OF PUBLIC HEALTH

1. Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and
2. The temperature of solutions in the tanks shall be maintained within the range of 60 °F to 80 °F (16 °C to 27 °C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the following time-temperature chart:

105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.403: continued

Time-Temperature Chart		
Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2½
25.0	77	2½
24.4	76	3
23.9	75	3
23.3	74	3½
22.8	73	3½
22.2	72	4
21.7	71	4
21.1	70	4½
20.6	69	4½
20.0	68	5
19.4	67	5½
18.9	66	5½
18.3	65	6
17.8	64	6½
17.2	63	7
16.7	62	8
16.1	61	8½
15.6	60	9½

3. Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

(b) Automatic processors and other closed processing systems:

(1) Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the following chart:

105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.403: continued

Developer Temperature		Minimum Immersion Time ^{a/}
°C	°F	Seconds
35.5	96	19
35.0	95	20
34.5	94	21
34.0	93	22
33.5	92	23
33.0	91	24
32.0	90	25
31.5	89	26
31.0	88	27
30.5	87	28
30.0	86	29
29.5	85	30
^{a/} Immersion time only, no crossover time included.		

2. The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor.

(c) Processing deviations from the requirements of 105 CMR 120.403(C)(1) shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (*e.g.*, extended processing, and special rapid chemistry).

(D) Quality Assurance tests for the processor shall be performed daily.

(E) Test tools for quality assurance tests for the processor shall include the following:

1. Densitometer
2. Sensitometer
3. Thermometer
4. Film

(F) Daily film processor quality assurance tests shall include:

1. Checking solution temperatures.
 - A. The developer temperature shall be as recommended by the film manufacturer.
 - B. Mercury thermometers are prohibited for determining solution temperatures.

(G) Determination and recording of the speed step. Maximum control limits shall not exceed +/- 0.15 optical density (OD).

(H) Calculation and recording of the contrast index or density difference. Maximum control limits shall not exceed +/- 0.15 optical density (OD)

(I) Measuring and plotting the Base + Fog. Maximum base plus fog density shall not exceed 0.25 optical density

105 CMR: DEPARTMENT OF PUBLIC HEALTH

(OD).

(J) Chemistry replenishment rates shall be measured and recorded semi-annually.

(K) Processor sensitometric tests results including speed index, contrast index, and base plus fog shall be plotted on control charts.

(L) Operating levels and control limits for processor quality assurance tests shall be indicated on the control chart.

(M) Quality assurance records shall be maintained for a minimum of 24 months and readily available for review by representatives of the Department.

(2) Other Requirements:

(a) Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

(b) The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

(1) Quality assurance tests for darkroom integrity shall be performed at least semi-annually.

(2) Each facility shall use pre-exposed film for performing quality assurance tests.

(3) No smoking or eating is permitted in the darkroom.

(4) The darkroom shall be kept free of dust.

(5) Counter tops, floors, and processing feed trays shall be cleaned daily before any films are handled or processed.

(c) Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

(d) Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

(e) Film cassettes and intensifying screens shall be kept free of artifacts and shall be cleaned regularly and replaced as necessary to best assure radiographs of good diagnostic quality.

(1) Screens shall be cleaned at intervals not to exceed one month with a screen cleaner recommended by the screen manufacturer. A copy of this requirement shall be kept in the darkroom.

(f) Outdated x-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

(g) Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

120.405: Fluoroscopic X-Ray Systems

All fluoroscopic x-ray systems shall meet the following requirements

(A) Limitation of Useful Beam.

(1) Primary Barrier.

(a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

(b) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

(2) Fluoroscopic Beam Limitation.

- (a) For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.
- (b) For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters table top to the film plane distance.
- (c) For uncertified fluoroscopic systems without a spot film device, the requirements of 120.405(A)(2)(a) apply.
 - 1. Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;
 - 2. All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less;
 - 3. If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of 5 centimeters by 5 centimeters or less;
 - 4. For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and,
 - 5. For non-circular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(3) Spot-film Beam limitation. Spot-film devices shall meet the following requirements:

- (a) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;
- (b) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4 percent of the SID;
- (c) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, five centimeters by five centimeters;

105 CMR: DEPARTMENT OF PUBLIC HEALTH

120.405: continued

- (d) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2% of the SID; and,
 - (e) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.
- (4) Override. If a means exists to override any of the automatic x-ray field size adjustments required in 105 CMR 120.405(A)(2), that means:
- (a) Shall be designed for use only in the event of system failure;
 - (b) Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and,
 - (c) Shall be clearly and durably labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

(B) Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(C) Exposure Rate Limits.

(1) Entrance Exposure Rate Allowable Limits.

- (a) Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except:
 - 1. During recording of fluoroscopic images; or,
 - 2. When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.
- (b) Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in a exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient, except:
 - 1. During recording of fluoroscopic images; or
 - 2. When an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(c) Fluoroscopic equipment which is provided with both automatic exposure rate control mode and a manual mode shall not be operable at any combination of tube potential and current which shall result in an exposure

105 CMR: DEPARTMENT OF PUBLIC HEALTH

rate in excess of 2.6 mC/kg (10 roentgens) per minute in either mode at the point where the center of the useful beam enters the patient, except:

1. During recording of fluoroscopic images; or
2. When the mode or modes have an optional high level control, in which case that mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient, unless high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(d) Any fluoroscopic equipment manufactured after May 19 1995 which can exceed 1.3 mC/kg (5 roentgens) per minute shall be equipped with an automatic exposure rate control. All entrance exposure rate limits shall be 2.6 mC/kg (10 roentgens) per minute with an upper limit of 5.2 mC/kg (20 roentgens) per minute when high level control is activated.

(e) Compliance with the requirements of 105 CMR 120.405(C) shall be determined as follows:

1. If the source is below the table, exposure rate shall be measured one centimeter above the tabletop or cradle.
2. If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

120.405: continued

3. For a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly;
4. For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.

(f) Periodic measurement of maximum entrance exposure rate shall be performed by a qualified expert for both typical and maximum values as follows:

1. Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate;
2. Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in 105 CMR 120.403(A)(2)(b). The measurement results shall be stated in coulombs per kilogram (roentgens) per minute and include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed shall be included in the results;
3. Conditions of periodic measurement of typical entrance exposure rate are as follows:
 - (a) The measurement shall be made under the conditions that satisfy the requirements of 105 CMR 120.405(C)(1)(c);
 - (b) The kVp, mA, and/or other selectable parameters shall be adjusted to those settings typical of clinical use on a 23 cm thick abdominal patient;
 - (c) The x-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliamperage and/or kilovoltage to satisfy the conditions of 105 CMR 120.405(C)(1)(d)3.; and,
4. Conditions of periodic measurement of maximum entrance exposure rate are as follows:
 - (a) The measurement shall be made under the conditions that satisfy the requirements of 105 CMR 120.405(C)(1)(c);
 - (b) The kVp, mA and/or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;
 - (c) The x-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum entrance exposure rate of the system.

(D) Barrier Transmitted Radiation Rate Limits.

(1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed two milliroentgen (0.516 $\mu\text{C/kg}$) per hour at ten centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(2) Measuring Compliance of Barrier Transmission.

- (a) The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- (b) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic

105 CMR: DEPARTMENT OF PUBLIC HEALTH

imaging assembly positioned 30 centimeters above the tabletop.

(c) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

120.405: continued

(d) Movable grids and compression devices shall be removed from the useful beam during the measurement.

(e) The attenuation block shall be positioned in the useful beam ten centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

(E) Indication of Potential and Current. During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.

(F) Source-to-Skin Distance. The SSD shall not be less than:

- (1) 38 centimeters on stationary fluoroscopes manufactured on or after August 1, 1974;
- (2) 35.5 centimeters on stationary fluoroscopes manufactured prior to August 1, 1974;
- (3) 30 centimeters on all mobile fluoroscopes; and,
- (4) 20 centimeters for image intensified fluoroscopes used for specific surgical application. The written safety procedures must provide precautionary measures to be taken during the use of this type of fluoroscope.

(G) Fluoroscopic Timer.

- (1) Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.
- (2) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

(H) Control of Scattered Radiation.

- (1) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.
- (2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:
 - (a) Is at least 120 centimeters from the center of the useful beam; or
 - (b) The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 105 CMR 120.403(A)(1)(e).
- (3) The Agency may grant exemptions to 105 CMR 120.405(H)(2) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Agency shall not permit such exemption. See 105 CMR 120.423: *Appendix D* for a suggested list of fluoroscopic procedures where such exemptions will be automatically granted.

(I) Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of 105 CMR 120.405(A), (C), (D) and (G) provided that:

105 CMR: DEPARTMENT OF PUBLIC HEALTH

- (1) Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and,
- (2) Systems which do not meet the requirements of 105 CMR 120.405(G) are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

(J) Spot film Exposure Reproducibility. Fluoroscopic systems equipped with spot film (radiographic) modes shall meet the exposure reproducibility requirements when operating in the spot film mode.

(K) Operator Qualifications.

- (1) The facility shall ensure that only a licensed practitioner of the healing arts or a radiologic technologist who is trained in the safe use of fluoroscopic x-ray systems shall be allowed to operate these systems. All persons using fluoroscopic x-ray systems shall have, at a minimum, additional training as specified in 105 CMR 120.405 (K)(2),
- (2) Training to meet requirements of 105 CMR 120.406(K)(1) shall include, but not limited to the following:
 - (a) Principles and operation of the fluoroscopic x-ray system;
 - (b) Biological effects of x-ray;
 - (c) Principles of radiation protection;
 - (d) Fluoroscopic outputs;
 - (e) High level control options;
 - (f) Dose reduction techniques for fluoroscopic x-ray systems; and
 - (g) Application requirements of these regulations.
- (3) The facility shall maintain all records to document the training requirements.
- (4) All facilities shall establish policies and procedures for restricting the use of fluoroscopic systems to only those physicians who have been granted privileges for the use of fluoroscopy based on a determination of adequate training and knowledge.
- (5) All facilities performing fluoroscopically-guided interventional procedures shall conduct patient dose evaluation for any procedure with a significant potential for large radiation dose to patients.
 - (a) Records documenting that procedures have been developed to determine those that have a potential to result in patient doses exceeding the threshold for injury have been established to reduce the probability of such exposures and that appropriate action occurs for patients receiving doses that warrant follow-up.
 - (b) The facility shall have patient dose monitoring procedures in place.
 - (c) The facility shall document in the patient's medical record the fluoroscopy time and an estimate of the absorbed dose to the skin.
 - (d) Any cumulative absorbed dose to the skin equal to or greater than 1 Gy (100 rads) must be noted in the patient's medical record and reviewed by the Radiation Safety Committee.
- (6) Each facility shall ensure that all non-radiologists using fluoroscopy equipment obtain annual training in Radiation

105 CMR: DEPARTMENT OF PUBLIC HEALTH

Safety/Radiation Protection and document this training.

(L) Equipment Operation.

- (1) Radiological technology students shall not be allowed to operate fluoroscopic x-ray systems unless directly supervised by a licensed practitioner of the healing arts or a licensed Radiological Technologist.
- (2) Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.
- (3) Facilities that use fluoroscopic x-ray systems shall maintain a record of the cumulative fluoroscopic exposure time used and the number of spot films for each examination. This record shall indicate patient identification, type of examination, date of examination, and operator's name.

120.406: Radiographic Systems Other Than Fluoroscopic, Computed Tomography Systems

(A) Beam Limitation~~Except for Mammographic Systems~~. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device meeting manufacturer's specifications and the requirements of 105 CMR 120.406~~(F)~~~~(G)~~(2) has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

105 CMR: DEPARTMENT OF PUBLIC HEALTH

as specified in 105 CMR 120.406(F)(6)(a) and (b)120.410 120.410(B)(1).

120.422: Appendix C -- Design Requirements for an Operator's Booth

(A) Space Requirements

- (1) The operator shall be allotted not less than 7.5 square feet (0.697 m²) of unobstructed floor space in the booth.
- (2) The operator's booth may be any geometric configuration with no dimension of less than two feet (0.61 m).
- (3) The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables or other similar encroachments.
- (4) The booth shall be located or constructed such that unattenuated direct scatter radiation originating in the examination table or at the wall cassette shall not reach the operator's station in the booth.

(B) Structural Requirements

- (1) The booth walls shall be permanently fixed barriers of at least seven feet (2.13 m) high.
- (2) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.
- (3) Shielding shall be provided to maintain exposure inside the booth equal to or less than two mR per week.

(C) X-Ray Control Placement. The x-ray exposure switch for the system shall be fixed within the booth and;

- (1) Shall be at least 40 inches (1.02 m) from any open edge of the booth and;
- (2) Shall allow the operator to use the majority of the available viewing windows.

(D) Viewing System Requirements.

- (1) Each booth shall have at least one viewing device which will:
 - (a) Be so placed that the operator can view the patient during any exposure; and,
 - (b) The device should be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door that allows access to the room cannot be seen from the booth, then that door must have an interlock controlling the exposure, which will prevent the exposure if the door is not closed.
- (2) When the viewing system is a window, the following requirements also apply:
 - (a) The viewing area shall be at least one square foot (0.0929 m²).
 - (b) The design of the booth shall be such that the operator's expected position when viewing the patient and operating the x-ray system is at least 18 inches (0.457m) from the edge of the booth.
 - (c) The material constituting the window shall have at least the same lead equivalence as that required in the booth's walls in which it is mounted.
- (3) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of 105 CMR 120.421: *Appendix -B* ~~C~~(A)(4).
- (4) When the viewing system is by electronic means:
 - (a) The camera shall be so located as to accomplish the general requirements of 105 CMR 120.421: *Appendix -B* ~~C~~(A)(4); and,
 - (b) There shall be an alternate viewing system as a backup for the primary system.
 - (c) Means shall be provided for the operator to be able to orally communicate with the patient at all times.

120.423: Appendix D --Exemptions From Shielding for Certain Fluoroscopic Procedures

- (A) Angiograms
- (B) Arthrograms
- (C) Biliary drainage procedures
- (D) Fluoroscopic biopsy procedures
- (E) Myelograms
- (F) Percutaneous cholangiograms
- (G) Percutaneous nephrostomies
- (H) Sinograms or fistulograms
- (I) T-tube cholangiograms